In the
United States Court of Appeals
For the Seventh Circuit

Nos. 06-3612 & 06-3619

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

v.

ROSS A. CAPUTO and ROBERT M. RILEY,

Defendants-Appellants.

Appeals from the United States District Court
for the Northern District of Illinois, Eastern Division.
No. 03 CR 126—**Ruben Castillo**, *Judge*.

ARGUED SEPTEMBER 10, 2007—DECIDED FEBRUARY 27, 2008

Before EASTERBROOK, *Chief Judge*, and KANNE and EVANS, *Circuit Judges*.

EASTERBROOK, *Chief Judge*. An autoclave sterilizes medical instruments quickly and cheaply. But some instruments can't stand the high temperatures and pressures of an autoclave, so there is a demand for sterilizers that use lower temperatures and non-aqueous sterilants. One system in widespread use relies on ethylene oxide gas as the sterilant. That gas is toxic and hard to handle, however, and Ross Caputo saw a business opportunity in these drawbacks. He designed a low-temperature

system using a plasma of peracetic acid as the sterilant and in 1990 asked the Food and Drug Administration to approve this device, which his company AbTox Inc. called the Plazlyte.

Since 1976 it has been unlawful to sell a new medical device without the FDA's approval. The Medical Device Amendments to the Food, Drug, and Cosmetic Act have a grandfather clause covering devices that had been lawfully sold on or before May 28, 1976, or are "substantially equivalent" to them. 21 U.S.C. §360c(f)(1)(A)(ii). AbTox asked the FDA to approve sales of a Plazlyte as "substantially equivalent" to units that employ ethylene oxide as the sterilant. We refer to "a" Plazlyte rather than "the" Plazlyte because AbTox made at least two models. The first had an interior volume of one cubic foot and used 10% peracetic acid made by mixing water with a solution of 30% peracetic acid. The water and the 30% solution were in separate bottles. This device used a two-cycle procedure, applying gas plasma twice to sterilize the instruments. The second model had an interior volume of approximately five cubic feet, used 5% peracetic acid from a single bottle (no dilution with water from a second bottle), and ran just one cycle, at a different pressure from the first model. We call the first model the small Plazlyte and the second model the large Plazlyte.

AbTox submitted the small Plazlyte for approval in 1990. It also submitted only those tests that favored the device's effectiveness; others, less helpful to AbTox, were concealed (or so a jury could conclude; we recount the evidence in the light most favorable to the verdict). The agency's staff doubted whether the Plazlyte was equivalent to ethylene oxide systems and insisted on limiting the uses to which it could be put. When the FDA

signed off on the small Plazlyte in 1994, it approved the device only for use with solid stainless-steel instruments. If AbTox wanted to sell the Plazlyte to sterilize instruments containing interior space that the gas plasma might not fully penetrate (such as those with hinges or lumens) or instruments made from materials that might react chemically with peracetic acid ($C_2H_4O_3$), an organic peroxide, it had to file an application for approval as a new device rather than one equivalent to a grandfathered device. Any medical instrument containing plastic, solder (usually made of lead, tin, or silver), or brass (an alloy of copper and zinc) was outside the scope of the FDA's approval.

A new and expensive machine (Plazlytes sold for about $100,000) for sterilizing solid instruments made of stainless steel had no prospect in the market. Autoclaves are cheaper and don't require the handling of acids. Caputo understood that AbTox would never be able to sell a single unit of the small Plazlyte for the limited use approved by the FDA. Caputo (and his assistant Robert Riley) did not try. Instead they immediately began promoting the large Plazlyte as a replacement for ethylene-oxide devices, and thus as suitable for general-purpose sterilization. It had begun selling the large Plazlyte outside the United States in 1993; thus, long before receiving the FDA's approval to sell the small Plazlyte, it knew that the small device would never be marketed and that the large Plazlyte would be promoted for use with many kinds of instruments—though it did not tell the FDA these things when negotiating the details of the limited use that would be allowed to the small Plazlyte.

Problems ensued when some hospitals used the Plazlyte to sterilize brass instruments employed for procedures

in the eye. The Plazlyte left a blue-green residue on some of these instruments—and, although the instruments were sterile, the residue (copper and zinc acetate) was harmful to patients' eyes. Some patients experienced corneal decompensation, a severe condition that entails loss of vision.

In May 1995 the FDA found out what AbTox was telling customers and reminded it about the limitations on the scope of approval. This notice informed AbTox that the Plazlyte as promoted was "misbranded". AbTox then sought the FDA's approval to sell the large Plazlyte to sterilize a wider class of instruments; when the FDA rejected AbTox's request for expedited decision and told AbTox that it "may not market this device until you have received a letter from the FDA allowing you to do so", AbTox went on promoting the large Plazlyte as before. On September 27, 1996, the FDA sent AbTox another instruction to stop selling the large Plazlyte; AbTox failed to comply (though it did not tell the FDA so). The agency never authorized AbTox to sell the large Plazlyte for any use.

The Centers for Disease Control opened an investigation to discover what was causing the eye injuries. Meanwhile, in January 1998, the FDA inspected AbTox's facilities and discovered that it was still selling the large Plazlyte. The inspectors told AbTox to desist; it didn't. In April 1998 the FDA issued a warning to all hospitals, telling them that the large Plazlyte was not an approved device and at all events must not be used with any instruments containing solder, copper, or zinc, or for any ophthalmic instruments. The FDA directed AbTox to recall the devices; U.S. marshals seized its inventory; this criminal prosecution eventually followed.

The prosecutor threw the book at Caputo and Riley. The indictment charged them with conspiring to defraud the United States, 18 U.S.C. §371, mail fraud, 18 U.S.C. §1341, wire fraud, 18 U.S.C. §1343, lying to federal agents, 18 U.S.C. §1001, and the delivery of misbranded devices, 21 U.S.C. §§ 331(a) and 333(a)(1). A jury convicted them of these charges after an eight-week trial. Caputo has been sentenced to 120 months' imprisonment and Riley to 72 months. Both were ordered to make restitution of $17.2 million, the list price of all Plazlyte units ever sold.

Defendants' lead argument is that the Food, Drug, and Cosmetic Act violates the first amendment by restricting promotional materials to those uses that the FDA has approved. The argument starts from the premise that federal law allows customers of any approved medical device or drug to put it to any use that the customer sees fit. These "off-label uses" being lawful, the argument goes, it must also be lawful to tell customers about them.

Until the last 30 years, such an argument would have been laughed out of court. *Valentine v. Chrestensen*, 316 U.S. 52 (1942), had held that "commercial speech"—that is, speech promoting a product for sale—is not part of the "freedom of speech" as that term was understood in 1789. But the Court overruled *Valentine* in *Virginia Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976), holding that the government cannot regulate by ensuring ignorance among consumers. If it is lawful to sell a product then, the Court held, it must be lawful to inform consumers that the product is available to buy. Consumers themselves must decide what to do; the Constitution forecloses an enforced ignorance based on a paternalistic view that informed consumers will make mistakes. See also, e.g., *Greater New Orleans Broadcasting*

Ass'n, Inc. v. United States, 527 U.S. 173 (1999); *Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995); *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60 (1983); R.H. Coase, *Advertising and Free Speech*, 6 J. Legal Studies 1 (1977).

For a time judges thought the Supreme Court's new understanding inapplicable to drugs (and, by implication, medical devices): Federal law allows vendors to tell customers about all lawfully available drugs and devices, after all, and thus avoids the precise problem presented by *Virginia Citizens Consumer Council*. But federal law *does* prohibit manufacturers from alerting consumers to lawful off-label uses, and *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002), held that this limit is unconstitutional in at least some applications. A federal law allowed pharmacists to compound some drugs that had been approved for stand-alone sales, creating substances that had not been subjected to the normal testing. The legislation granting pharmacists this compounding privilege attached conditions to the way they could promote the compounded drugs. The Court held these limits unconstitutional: if the compounded drug could be sold, the Court held, then it could be freely promoted for every lawful use. *Western States Medical Center* establishes that drugs are not a special case for first-amendment analysis. (The Court once held that gambling is a special case, see *Posadas de Puerto Rico Associates v. Tourism Co. of Puerto Rico*, 478 U.S. 328 (1986), but the status of that rule is doubtful. See *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 508–14 (1996) (plurality opinion).) The Court suggested in *Western States Medical* that Congress either adopt a substantive rule prohibiting compounding (or, here, prohibiting off-label uses) or allow the FDA to supply warnings via its own speech. Compelling private

persons to toe the government's line, or shut up, is unconstitutional, the Court held. This is the doctrine that Caputo and Riley propose to invoke in their defense.

Whether *Virginia Citizens Consumer Council* and *Western States Medical Center* apply to promotion by a product's manufacturer, which struck a bargain with the FDA in the approval process by promising to limit its promotion—a bargain that the private litigants in the earlier cases had not struck—is a difficult question. The doctrine of unconstitutional conditions places limits on the promises that an agency may extract from those who seek approval. And if a given use is lawful, and thus can be written about freely in newspapers or blogs, and discussed among hospitals that already have purchased a Plazlyte, doesn't it make a good deal of sense to allow speech by the device's manufacturer, which after all will have the best information? Why privilege speech by the uninformed? The manufacturer has an incentive to slant the speech in its favor and may withhold bad news, but many listeners (especially professionals such as physicians) understand this and can discount appropriately. That, at any rate, is the anti-paternalist view of *Virginia Citizens Consumer Council* and the cases that followed in its wake.

Yet if a manufacturer's promise to the FDA to avoid speech about off-label uses is unenforceable, the FDA may respond by withholding any approval of drugs or devices that have questionable additional uses. AbTox's small Plazlyte would not have been approved at all, had the FDA anticipated that approval would enable AbTox to tout it (or its larger brother) for use with brass ophthalmic instruments. Other firms, with no desire to promote off-label uses (or, at least, no desire to pay for the expensive tests needed to persuade the FDA to sanc-

tion wider use), would be made worse off by their inability to strike deals allowing the FDA to approve a subset of all possible uses. Consumers who could benefit from drugs or devices that would be excluded from the market by the FDA's response to a broad privilege to tout off-label uses also would be made worse off. Doubtless the first amendment differs from Bentham's felicific calculus, but a court should hesitate before extending an ahistorical reading of the Constitution in a way that injures the very audience that is supposed to benefit from free speech.

Fortunately, we need not decide today whether a seller of drugs or medical devices has a constitutional right to promote off-label uses. *Virginia Citizens Consumer Council* and its successors rest on the assumption that the law allows the activity that the speaker seeks to promote. Here that assumption holds only if AbTox lawfully could sell the large Plazlyte for the (approved) use with solid stainless-steel instruments. Unless the machine itself could be sold lawfully, there were no lawful off-label uses to promote. And the jury found, by its verdicts on both the fraud-on-the-United-States count and the misbranded-device counts, that the large Plazlyte could *not* lawfully be sold. The jury concluded not only that Caputo and Riley had lied to the agency when seeking approval of the small Plazlyte but also that the large Plazlyte differed enough from the small one that new approval was essential. For current purposes it is enough to concentrate on the latter conclusion. (Defendants insisted at oral argument that the jury could have convicted, under the instructions given, without finding either lies to the FDA or sale of a never-approved device. We have reviewed the instructions and

conclude that, to convict on all counts as it did, the jury had to find both.)

Once the FDA certifies a medical device under the grandfather clause, the seller may make modifications to that device without obtaining fresh approval. The line between a "modification" (no approval needed) and a new device (which must be submitted independently for approval) is drawn in 21 C.F.R. §807.81. There are two principal inquiries: first, whether the changes "significantly affect the safety or effectiveness of the device" and, second, whether there is a "major change or modification in the intended use of the device." 21 C.F.R. §807.81(a)(3). We doubt that the large Plazlyte could be described as a "modification" of the small one; recall that the large device had been placed on sale outside the United States in 1993, the year before the FDA approved the small device. "Modification" suggests a change in an approved device, not a different device that was already on sale before the approval. But suppose that this is wrong, and suppose further that the large Plazlyte was as safe as the small one notwithstanding the difference in the concentration and number of applications of the sterilant. There remains the rule that a "major change or modification in the intended use of the device" requires fresh approval. Promoting the large Plazlyte as suitable for use with all medical instruments is a major change in intended use, compared with using it for solid stainless-steel instruments alone. This expansion of use caused the copper and zinc acetates that injured patients. So the large Plazlyte, with its expanded "intended use", was not covered by the FDA's approval of the small Plazlyte and could not lawfully be sold *at all*. That knocks out the premise of *Virginia Citizens Consumer Council* and similar cases. There was no lawful activity for speech to promote.

Caputo and Riley try to avoid this conclusion by arguing that the Due Process Clause of the fifth amendment disabled the FDA from keeping the large Plazlyte off the market. The line between new and modified devices is too vague to be enforceable, the argument goes. We grant that phrases such as "significantly affect" and "major change . . . in the intended use" are not self-defining. But then no legal phrase is. Think of "material" (as in "material misrepresentations are forbidden"), a staple of legal discourse, or "unreasonable" (as in "unreasonable danger to the health and safety of park users", a phrase deemed adequately specific in *Thomas v. Chicago Park District*, 534 U.S. 316, 324 (2002)). The Supreme Court has rejected vagueness challenges to the antitrust laws, see *Nash v. United States*, 229 U.S. 373 (1913), which must be an order of magnitude more ambulatory than §807.81(a)(3), and has held that a rule cannot be deemed unconstitutionally vague if it suggests a metric for decision. See *United States v. Powell*, 423 U.S. 87 (1975). Section 807.81(a)(3) tells us what dimensions of difference matter, even though it does not give an exact answer to the question "how much is too much"? (The statute in *Powell*, which forbade the mailing of a firearm capable of being concealed on the person, also omitted a quantitative rule, but the Court held that its qualitative approach suffices.)

The uncertainty that is inevitable in legal standards (as opposed to numerical rules) often is offset by notice, so that people need not guess what is required of them. The FDA gave AbTox notice, and to spare. It published in March 1993 (before the small Plazlyte was approved) a "Guidance" stating that any change in the sterilant or chamber size of a sterilizer creates a new device that

requires new approval. It sent letters, which AbTox ignored. (The letters not only called attention to the 1993 Guidance but also restated the FDA's view of AbTox's duties under the statute and regulation.) It sent an inspection team, whose directions AbTox spurned. There was no such notice in *United States v. Prigmore*, 243 F.3d 1 (1st Cir. 2001), a decision on which defendants heavily rely. (And *Prigmore* did not hold the statute or regulations unconstitutionally vague, either, though it did remand for a new trial with jury instructions adequate to pin down the meaning of the rules at issue there.)

To say that the FDA showered interpretations and advice on Caputo and Riley is not to say that the published "Guidance" has the effect of a regulation, let alone that AbTox was legally bound to comply with the letters. Only the statute, regulations, and formal directives of the agency (as opposed to its staff) have legal force. The agency did not issue its cease-and-desist and recall orders until April 1998. Until then Caputo and Riley were at liberty to chart their own course, as their own legal advisers counseled them. When they did this, however, they took a risk and could not then say "we didn't know" or "the regulation left us scratching our heads." The agency comprehensively alerted AbTox, Caputo, and Riley to its view of their legal obligations, and an agency's interpretation of its own regulations, no less than a judicial opinion, may disambiguate them. When Caputo and Riley chose to go their own way, the question on the table for the court became simply who is right about the meaning of the legal rules, not whether adequate notice was given.

Note that Caputo and Riley have not made an advice-of-counsel defense, though no one gets into a multi-million-

dollar medical-device business without legal counsel. Perhaps they lied to their lawyers about what they were doing and thus cannot present a defense that depends on candor to counsel; or perhaps they decided to avoid asking for advice about §807.81(a)(3) for fear of what the answer would be; finally, they may have asked and received a reply that they did not follow. The attorney-client privilege prevents us from knowing which.

Defendants did, however, argue that they acted "in good faith." They complain about the adequacy of the instructions on this subject. That the district judge gave any such instruction at all was unduly favorable to the defense. This was at heart a fraud prosecution (and for most counts nothing but a fraud prosecution), and there is no "good faith defense" to fraud. A person who tells a material lie to a federal agency can't say "yes, but I thought it would all work out to the good" or some such thing. Intentional deceit on a material issue is a crime, whether or not the defendant thought that he had a good excuse for trying to deceive the federal agency or the potential customers.

The district judge did not abuse his discretion—the right standard, see *General Electric Co. v. Joiner*, 522 U.S. 136 (1997)—in keeping out of evidence the proposed "expert" testimony that defendants wanted to introduce. The "expert" would have testified about the meaning of the statute and regulations. That's a subject for the court, not for testimonial experts. See *Bammerlin v. Navistar International Transportation Corp.*, 30 F.3d 898, 900 (7th Cir. 1994). The only legal expert in a federal courtroom is the judge. An advice-of-counsel defense might have got something along these lines in through the back door, but as we have explained no such defense was made.

It came out after the trial that the jury's foreman had six misdemeanor convictions related to his use of heroin and alcohol, to which he had been addicted. The district judge held a hearing and concluded that this juror had believed that questions asking the venire whether anyone had been convicted of a crime sought information about federal crimes only, and he had not been convicted of a federal crime. The judge credited that explanation, found that the juror had committed an "honest mistake," and added that, had the juror revealed his convictions, they would not have supported a challenge for cause. The juror testified, and the judge found, that he had broken his heroin addiction through a methadone program, had been "clean" for a year before trial, and had been forthright about his problems when asked; it was a newspaper report, based on that candor, that led to the discovery after the end of the trial. The district judge applied the right legal standard, see *McDonough Power Equipment, Inc. v. Greenwood*, 464 U.S. 548 (1984); *United States v. Warner*, 498 F.3d 666, 684–88 (7th Cir. 2007), and did not abuse his discretion in concluding that defendants are not entitled to a new trial. After all, it is usually the prosecutor who wants to excuse potential jurors with criminal records, lest they sympathize unduly with others facing the ordeal of a prosecution and at risk of imprisonment. Caputo and Riley do not give any reason for thinking that this juror would have been slanted in the prosecutor's favor.

Riley contends that his conviction on Count 9, which charged him with making two false statements to an employee of the FDA, in violation of 18 U.S.C. §1001, should be reversed because the instructions allowed the jury to convict if either of two statements was false,

while the evidence shows that one statement at most was false. As a matter of law, one false statement is enough for a conviction, so Riley's line of argument fails under *Griffin v. United States*, 502 U.S. 46 (1991), which holds that a conviction is proper if the evidence established beyond a reasonable doubt any of the ways in which the crime might have been committed. *Griffin* holds that a jury may be relied on to accept the supported possibility and discard the unsupported one. (When the instruction contains a legal error, then the jury's fact-finding ability may lead it astray, but Riley does not contend that the instruction allowed the jury to convict him on Count 9 on a factually substantiated but legally incorrect theory.)

A brief discussion of sentencing brings this opinion to a close. The district court calculated the loss at roughly $17 million, the list price for all Plazlyte devices that AbTox delivered. Application Note 3(F)(v) to U.S.S.G. §2B1.1 says that defendants who sell goods without required approvals receive no credit for their value, if any, to the customers. List price thus was the right starting point. Defendants say, however, that some machines were sold at a discount and a few given away as demonstrators, and that the judge should have used actual transactions prices rather than list prices. That's true in principle, but defendants don't say that using transactions prices would have reduced the loss below $7 million. A loss from $7 million through $20 million produces the same offense level; there's accordingly no need to determine with precision where within that span the loss falls. (Despite *United States v. Demaree*, 459 F.3d 791 (7th Cir. 2006), which was released a month before defendants were sentenced and holds that judges must use the Guide-

lines in force on the date of sentencing, the district judge used the 1997 version in which loss from $10 million through $20 million produced the same number of levels. That error was favorable to defendants, and as the prosecutor has not taken a cross-appeal we need not discuss it further.)

Finding actual transactions prices was unnecessary to know the "loss" for the purpose of §2B1.1, which does not require more than an estimate. Restitution, by contrast, requires an exact figure; it is a substitute for civil damages, though limited to direct losses rather than consequential damages. See *United States v. Behrman*, 235 F.3d 1049 (7th Cir. 2000); *United States v. Havens*, 424 F.3d 535, 537 (7th Cir. 2005). So the restitution for a Plazlyte with a list price of $100,000 but sold at a $20,000 discount is $80,000, not $100,000. And the restitution for a machine given away as a demonstrator is nothing. Likewise restitution for a machine that was invoiced at $100,000, but never paid for in light of the recall (defendants say that there were several in this category), is zero. The district court must determine these figures one customer at a time and not use the list-price shortcut that is suitable when the only question is whether loss falls within widely spaced bounds.

Defendants propose a further adjustment for the value the buyers obtained from the Plazlyte sterilizers. Some hospitals may have used them principally for the approved purpose and found them entirely satisfactory; others may have put them to off-label uses that did not cause problems. But if a court is going to deduct for the value of the machines in use, it should order restitution for the cost of compensating injured patients, the cost to hospitals and the Centers for Disease Control of investi-

gating the mysterious eye injuries, and so on; one can't have the subtractions for productive use without the additions for harms caused by off-label uses. Defendants do not propose to make restitution for these harms, so they can't obtain subtractions either.

There remains one problem: What of the machines that remained in service after the recall? A recall notice is (from a customer's perspective) an option rather than a command. Some hospitals returned their Plazlyte machines; others junked them; but a few kept them and continued using them, even purchasing extra sterilant from AbTox to extend their lives. (The FDA allowed AbTox to sell the peracetic acid to hospitals that certified their awareness of the recall and the reasons behind it.) These customers evidently believed that the machines were valuable—and, if hospitals took care to avoid certain kinds of instruments, they continued to be safe. We think that no restitution is owed to customers that, with full knowledge, continued to operate Plazlyte machines for longer than was necessary to replace them. (Hospitals that retained the Plazlyte sterilizers only until they could secure new, approved equipment should be grouped with hospitals that returned them in the recall.) In principle hospitals that kept their machines in long-term service are entitled to compensation for a reduction in the value that Plazlyte sterilizers would have on resale (not only because of the blow to their reputation but also because spare parts will be hard to come by), but unless that value (or its proxy, the reduction in the machines' expected useful lives) can be determined, the judge should assume that the hospitals that kept their Plazlyte machines for more than a year after the recall notice will use them until they wear out.

The judgment of the district court is affirmed except with respect to restitution. The award of restitution is vacated and the case remanded for calculation, using the principles in this opinion, of the amount that defendants owe to each of AbTox's customers.